Remarks/Arguments

Claims 1-17 and 20-23 are pending in the application. Claims 1-13 and 20-22 have been withdrawn from consideration pursuant to a lack of unity objection. Claim 18 is canceled by the present amendment. Claim 23 is new. Claim 23 is supported by claim 18. Claims 14-17 and 23 are under consideration.

Claim 19, which was previously cancelled, is listed as cancelled in the herein Listing of Claims, as suggested by Examiner.

Claims 14 and 15 have been amended to more particularly point out and define the invention over the prior art of record. Support for the amendment of claims 14 and 15 is found at page 3, lines 6-14 and page 4, lines 1-6.

Response to Section 102 Rejection

Claims 14-18 have been rejected as being anticipated by Tunnicliffe et al. (WO 98/24882) or Tunnicliffe et al. (US 6,468,782).

Tunnacliffe discloses methods of *drying and stabilizing* prokaryotic cells. Such methods require the performance of a defined 2 step process; the first step being the induction of trehalose production within the cell. The second step is the drying of the cells in order to form a solid glass.

Tunnacliffe does not identify the fact that cells in which trehalose has been induced are more immunogenic than cells in which intracellular trehalose is produced. Tunnacliffe does not explicitly compare the immunogenic activity of prokaryotic cells with or without intracellular trehalose induction. Rather, the consideration in Tunnacliffe relating to the effect of increasing the intracellular levels of trehalose relate solely to an increase in storage stability.

Examiner refers applicant to the fact that the discovery of a previously unappreciated property of a prior art composition does not render the composition patentably new.

Instant claim 14 defines an immunogenic composition wherein intracellular trehalose production is induced within a prokaryotic cell and further where that cell can be used to induce immunity *without* the cell having been subjected to the process of drying.

Such a composition is not disclosed in Tunnacliffe. In order to achieve the stated invention of Tunnaclife, that is, in order to maintain cells in a dried, stable form, it is necessary to dry the cells in the presence of a stabilizing agent.

Further, in order to produce cells according to the method of Tunnacliffe which would be suitable for use in live bacterial vaccines, it would be appreciated by the skilled artisan, following consideration of Tunnacliffe, that both the initial trehalose inducing and subsequent freeze drying steps would be required in order to produce cells which were viable. Tunnacliffe discloses only that the cells prepared according to the methods described therein could be used for live bacterial vaccines *in a dry stable form* (see column 4, line 32). Accordingly, the skilled artisan would not look to Tunnacliffe for guidance on the preparation of live bacterial vaccines which were in a form *other than* a dry, stabilized form. Thus, the skilled artisan would not be taught in Tunnacliffe of a composition according to the instantly claimed invention, which could be used to induce immunity – namely a prokaryotic cell or cell residue of a prokaryotic cell, which cell has been treated to increase the concentration of trehalose therein without subsequent drying of the cell in the presence of a non-reducing carbohydrate.

Further, the skilled artisan would not be motivated to forego the drying step of Tunnacliffe and use the cells once the level of intracellular trehalose had been induced in order to induce immunity as there is no suggestion in Tunnacliffe that such cells would be more immunogenic over cells which did not have the level of intracellular trehalose increased therein.

Reconsideration and withdrawal of the Section 102 rejection is respectfully submitted.

Conclusion

The claims of the application are believed in condition for allowance. An early action toward that end is earnest solicited.

Respectfully submitted
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